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June 2, 2004

BY FIRST CLASS MAIL

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857

Re: Freedom of Information Act Request Regarding Jerome Stevens Pharmaceuticals Formal Dispute Resolution

Dear Sir or Madam:

Pursuant to the Freedom of Information Act, 5 USC 552, we hereby request copies of all disclosable records relating to the formal dispute resolution initiated by Jerome Stevens Pharmaceuticals ("JSP") on or about May 23, 2003. This proceeding concerned the Food and Drug Administration's ("FDA's") refusal to file ("RTF") JSP's supplemental new drug application ("NDA") dated March 26, 2003, and is described more fully in JSP's March 31, 2004, amendment to its citizen petition. *See* Docket No. 04P-0061 (attached at Tab 1).

Subject to the definition below, this request includes, but is not limited to, all of the following:

- March 26, 2003: JSP's supplemental NDA 21-210/S-003, seeking to establish the therapeutic equivalence of Unithroid® to Synthroid®, including all bioequivalence studies submitted to FDA.
- May 13, 2003: Letter from FDA's Division of Metabolic and Endocrine Drug Products to JSP informing JSP of the RTF decision.
- May 23, 2003: JSP's response to FDA requesting a meeting and appealing FDA's decision to the Office of Drug Evaluation II ("ODE II").

- June 30, July 23, and July 25, 2003: JSP's submissions to FDA's Office of Chief Counsel.
- October 3, 2003: Letter from ODE II to JSP upholding FDA's decision.
- November 20, 2003: Letter from JSP to FDA appealing FDA's decision to the Office of New Drugs ("OND").
- December 19, 2003: Letter from OND to JSP granting JSP's request for a meeting in January 2004.
- January 20, 2004: Background materials submitted by JSP to FDA in preparation for the January 23, 2004, meeting.
- January 23, 2004: All minutes and other materials, including slides, from the meeting between JSP and FDA.

In addition, we specifically request all subsequent correspondence relating to this formal dispute resolution, including any letters from FDA granting or denying JSP's dispute resolution.

Generally, the term "records" means any written, typed, printed, photocopied, photographic, machine-readable, or magnetically or optically recorded matter of any kind, including agreements, correspondence, memoranda, reports, analyses, studies, proposals, notes, minutes, summaries, electronic mail, facsimile transmissions, slide presentations, notices, notebooks, and data stored on computer-readable media, such as electromagnetic or other disks, diskettes, hard disk drives, tapes, cartridges, and CD-ROM.

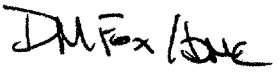
We believe that none of the requested records is exempt from disclosure under 5 USC 552(b). To the extent that you conclude otherwise, please provide an index of the records or portions of records that you claim are exempt from disclosure which sets forth a description of each such record or portion of record, the specific exemption that you claim applies, and the reasons why you claim the exemption applies.

Pursuant to 5 USC 552(b), if you assert that a portion of any requested record is exempt, please produce all remaining portions of the record which are reasonably segregable from the portion that you claim is exempt and indicate on the record the amount and location of the material that has been redacted. If you

assert that any remaining portions of the record are not reasonably segregable from the portion that you claim is exempt, please state the reasons for that assertion.

You may take this request as an agreement and assurance that whatever search and reproduction costs are involved, as set forth in 21 CFR 20.42, will be acceptable without prior authorization, up to a limit of $2,500.00. Please contact me at (202) 637-5678 if you have any questions regarding this request. We look forward to your prompt response.

Sincerely,



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